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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,905

01/25/2007

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80712-1110

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01/19/2011

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EXAMINER

COLELLO, ERIN L

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

01/19/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,905	Applicant(s) GUETTY, RICHARD JEAN-CLAUDE	
	Examiner ERIN COLELLO	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,14-17,19-27,30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,14-17,19-27,30 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed November 9, 2010.

Claims 2, 13, 18, 28-29, have been canceled without prejudice. Claims 1, 3-11, 14-17, 19-27, 30 and 32 are pending and an action on the merits is as follows.

Applicant's arguments filed November 9, 2010 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 17 recites the limitation "the stomach" in line 2 of claim 17. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 states “locking the cartridge in the closed configuration” in line 14 and then further states “and locking the cartridge in substantially the shape of the sleeve” which is vague and indefinite because it is not fully understood how the cartridge is locked into the shape of the sleeve after the cartridge is locked in the closed configuration. The Examiner suggests amending the claim to state that the locking step further comprises locking the cartridge in substantially the shape of a sleeve or something similar in order to clarify that there is only one locking step. Correction is needed

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-5, 9-10, 14, 17, 19-21, 25-26 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by **Garren et al. (US 4,899,747)**

Regarding claim 1, Garren discloses a kit for introducing an gastric implant into a stomach of a patient to treat obesity, the kit comprising: an intragastric implant for implanting in the stomach in order to reduce its volume (Ref 10, 10A; Column 2, lines 8-21; column 3, lines 30-51), said implant being expandable from a configuration for introduction into the stomach (Ref 10, 10A; Figures 9-10) to a therapeutic configuration within the stomach (Ref 10, 10A; Figure 11); and a cartridge for packaging said implant in the introduction configuration (Ref 20A), said cartridge being provided with an opener

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member activatable by positive action (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; wherein the free end of the drawstring is the opener member), enabling the cartridge to pass from a closed configuration in which the cartridge confines the implant in the implant's introduction configuration (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; Figures 9-10), to an open configuration in which the cartridge allows said implant to expand (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; Figure 11); wherein the cartridge including locking means functionally connected to the opener member and capable on its own, without requiring any external action on said locking means, of holding the cartridge in the closed configuration (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; wherein the drawstring is being interpreted as the locking means and the proximal free end is the opener member; wherein the zig-zag configuration of the drawstring allows the drawstring to maintain the cartridge in the closed configuration without any external action), said cartridge further comprises a sleeve (Ref 20A) provided with at least one side opening formed along its length (Ref 32), said opening being closed by said locking means when said cartridge is in the closed configuration (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30), and said opening being disengaged to allow the implant to expand when said cartridge is in the open configuration (Ref 32; Figure 11).

Regarding claim 3, Garren discloses that the sleeve is substantially tubular in shape (Ref 20A) and is slit along all or part of its length, said slit constituting the side opening (Ref 32).

Regarding claim 4, Garren discloses that the sleeve is made of a material that is flexible, but substantially not substantially elastic (Ref 20A; wherein the device is capable of changing configurations from a closed configuration to an open configuration and can therefore be interpreted as flexible).

Regarding claim 5, Garren discloses that the sleeve is made of a fabric having two opposite edges (Ref 20A, 32; wherein the two opposite edges are formed by the slit) locked together by the locking means so that the fabric takes up a substantially tubular shape (Ref 38, 32; Column 4, lines 61-68; Column 5, lines 1-30).

Regarding claim 9, Garren discloses that the cartridge (Ref 20A) is provided with a thread (Ref 38) having a first portion sewn as a single-thread chain stitch so as to form said locking means (Ref 38; wherein the first portion is the portion that zig-zags through the openings 34 to form a chain stitch), and having a second portion that remains free and forms the opener member that can be actuated in traction (Ref 38; wherein the second portion is the free end that passes proximally through the inside of the cartridge).

Regarding claim 10, Garren discloses that the periphery of the side opening (Ref 32) is provided with eyelets for being assembled together by single-thread chain-stitch sewing in order to close said opening (Ref 34; Column 4, lines 61-68; Column 5, lines 1-30).

Regarding claim 14, Garren discloses that the intragastric implant is an intragastric balloon comprising a first flexible bag defining a predetermined inside volume (Ref 10, 10A; Column 2, lines 11-21; Column 3, lines 30-51; Column 4, line 23-

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25), said first flexible bag being provided with first connection means for receiving a connection member for connection to a first source of a fluid in order to enable said first bag to be expanded in the stomach by being filled with the fluid (Column 3, lines 64-67; Column 4, lines 1-8; Ref 10, 10A, 22).

Regarding claim 17, Garren discloses a cartridge (Ref 20A) for introducing an intragastric implant into the stomach of a patient in order to treat obesity (Ref 10, 10A; Column 2, lines 8-21; Column 3, lines 30-51), said implant being designed to be implanted in the stomach in order to reduce its volume and being expandable from a configuration for introduction into the stomach (Ref 10, 10A; Figures 9-10) to a therapeutic configuration within the stomach (Ref 10, 10A; Figure 11), said cartridge being designed to package said intragastric implant in the introduction configuration (Ref 20A; Figures 9-10) and being provided with an opener member activatable by positive action (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; wherein the free end of the drawstring is the opener member) enabling the cartridge to pass from a closed configuration in which the cartridge confines the intragastric implant in the intragastric implant's introduction configuration (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; Figures 9-10), to an open configuration in which the cartridge allows said intragastric implant to expand (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; Figure 11); said cartridge including locking means functionally connected to the opener member and capable on its own, without any external action on said opener means, of holding the cartridge in the closed configuration (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; wherein the drawstring is being interpreted as the locking means and the

proximal free end is the opener member; wherein the zig-zag configuration of the drawstring allows the drawstring to maintain the cartridge in the closed configuration without any external action), said cartridge further comprises a sleeve (Ref 20A) provided with at least one side opening formed in its length (Ref 32), said side opening being closed by said locking means when said cartridge is in the closed configuration (Ref 32; Column 4, lines 61-68; Column 5, lines 1-30), and said opening being disengaged to allow the surgical implant to expand when said cartridge is in the open configuration (Ref 32, 10A; Figure 11).

Regarding claim 19, Garren discloses that the sleeve is substantially tubular in shape (Ref 20A) and is slit along at least a part of its length, said slit constituting said side opening (Ref 32).

Regarding claim 20, Garren discloses that the sleeve is made of a material that is flexible, but substantially not substantially elastic (Ref 20A; wherein the device is capable of changing configurations from a closed configuration to an open configuration and can therefore be interpreted as flexible).

Regarding claim 21, Garren discloses that the sleeve is made of a fabric having two opposite edges (Ref 20A, 32; wherein the two opposite edges are formed by the slit) locked together by the locking means so that the fabric takes up a substantially tubular shape (Ref 38, 32; Column 4, lines 61-68; Column 5, lines 1-30).

Regarding claim 25, Garren discloses that the cartridge (Ref 20A) is provided with a thread (Ref 38) having a first portion sewn as a single-thread chain stitch so as to form said locking means (Ref 38; wherein the first portion is the portion that zig-zags

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through the openings 34 to form a chain stitch), and having a second portion that remains free and forms the opener member that can be actuated in traction (Ref 38; wherein the second portion is the free end that passes proximally through the inside of the cartridge).

Regarding claim 26, Garren discloses that the periphery of the side opening (Ref 32) is provided with eyelets for being assembled together by single-thread chain-stitch sewing in order to close said opening (Ref 34; Column 4, lines 61-68; Column 5, lines 1-30).

Regarding claim 30, Garren discloses a method of manufacturing a kit for introducing an intragastric implant into a stomach of a patient to treat obesity, the method comprising the steps of: supplying or making an intragastric implant for implanting in said stomach (Ref 10, 10A; Column 2, lines 8-21; Column 3, lines 30-51), said implant being expandable from a configuration for introduction in the stomach (Ref 10, 10A; Figures 9-10) to a therapeutic configuration within the stomach (Ref 10, 10A; Figure 11); supplying or making a cartridge for packaging said implant in the introduction configuration (Ref 20A); and providing said cartridge with an opener member (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; wherein the free end of the drawstring is the opener member) activatable by positive action enabling the cartridge to pass from a closed configuration in which the cartridge is suitable for confining the implant in the intragastric implant's introduction configuration (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; Figures 9-10), to an open configuration in which the cartridge is suitable for allowing said implant to expand (Ref 38; Column 4,

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lines 61-68; Column 5, lines 1-30; Figure 11); and locking the cartridge in the closed configuration, in which the cartridge is provided with locking means capable on its own, without requiring any external action on said locking means, of holding the cartridge in the closed configuration (Ref 38; Column 4, lines 61-68; Column 5, lines 1-30; wherein the drawstring is being interpreted as the locking means and the proximal free end is the opener member; wherein the zig-zag configuration of the drawstring allows the drawstring to maintain the cartridge in the closed configuration without any external action) and locking the cartridge in substantially the shape of a sleeve, the sleeve including at least one axial opening at one of the ends of said sleeve (Ref 20A; Figure 11)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6, 11, 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Garren et al. (US 4,899,747)** in view of **Armstrong et al. (US 6,315,792 B1)**.

Regarding claims 6 and 22, Garren discloses all of the claimed limitations above but fails to explicitly disclose that the fabric is made of woven polyamide threads.

However, Armstrong teaches that it is well known in the art to make a knit-braid cover for covering an implantable medical device out of threads or fibers such as

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polyamide threads in order to form a tight cover which allows radially constraining forces to be uniformly distributed over the surface of the device while retaining excellent flexibility (Column 3, lines 29-49; Column 10, lines 25-41)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the fabric of Garren to comprise woven polyamide threads as taught by Armstrong, since such a modification forms a tight cover which allows radially constraining forces to be uniformly distributed over the surface of the device while retaining excellent flexibility.

Regarding claim 11, Garren discloses eyelets situated close to and along the edges (Ref 34) but fails to explicitly disclose that the fabric can be a mesh fabric; wherein meshes are formed.

However, Armstrong teaches that it is well known in the art to make a knit-braid cover for covering an implantable medical device out of threads or fibers such that meshes are formed in the fabric along the edges in order to form a tight cover which allows radially constraining forces to be uniformly distributed over the surface of the device while retaining excellent flexibility (Column 3, lines 29-49; Column 10, lines 25-41)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the fabric of Garren to comprise woven polyamide threads as taught by Armstrong, since such a modification forms a tight cover which allows radially constraining forces to be uniformly distributed over the surface of the device while retaining excellent flexibility.

Regarding claim 27, Garren discloses that the sleeve is made of a fabric having two opposite edges (Ref 20A, 32; wherein the two opposite edges are formed by the slit) locked together by the locking means so that the fabric takes up a substantially tubular shape (Ref 38, 32; Column 4, lines 61-68; Column 5, lines 1-30); and eyelets situated close to and along said edges (Ref 34) but fails to explicitly disclose that the fabric can be a mesh fabric; wherein meshes are formed.

However, Armstrong teaches that it is well known in the art to make a knit-braid cover for covering an implantable medical device out of threads or fibers such that meshes are formed in the fabric along the edges in order to form a tight cover which allows radially constraining forces to be uniformly distributed over the surface of the device while retaining excellent flexibility (Column 3, lines 29-49; Column 10, lines 25-41)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the fabric of Garren to comprise woven polyamide threads as taught by Armstrong, since such a modification forms a tight cover which allows radially constraining forces to be uniformly distributed over the surface of the device while retaining excellent flexibility.

8. Claims 7-8 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Garren et al. (US 4,899,747)** in view of **DeVries et al. (US 2004/0087976)**.

Regarding claims 7-8 and 23-24, Garren discloses all of the claimed limitations above but fails to explicitly disclose that at least a portion of the structure of the cartridge is covered in a coating.

However, DeVries teaches that it is well known in the art to coat a tubular device with a variety of suitable materials known in the art including a polyurethane coating and a lubricating material in order to allow easier passage through the esophagus (Paragraph [0083]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the kit of Garren to include a coating as taught by DeVries since such a modification helps provide an easier passage through the esophagus.

9. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Garren et al. (US 4,899,747)** in view of **Stern (US 3,211,152)**.

Regarding claims 15 and 16, Garren discloses all of the claimed limitations above but fails to explicitly disclose that the balloon includes at least one second flexible bag of predetermined volume and provided with second connection means so as to enable it to be connected to a second source of fluid.

However, Stern teaches that it is well known in the art for a device to include a first inflatable bag and a second inflatable flexible bag of smaller volume than the first bag and located inside of the first bag; wherein the second bag has second connection means and a second source of fluid in case the first outer bag is accidentally deflated by puncturing during surgery (Column 1, lines 38-58)

It would have been obvious to one of ordinary skill in the art at the time invention was made to include a second flexible bag of smaller volume within the first bag as

taught by Stern, since such a modification allows the device to remain inflated in case the first outer bag is accidentally deflated by puncturing during surgery.

10. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Garren et al. (US 4,899,747)** in view of **Campbell et al. (US 6,984,242)**.

Regarding claim 32, Garren discloses the step of inserting the surgical implant (Ref 10,10A) in the sleeve (Ref 20A) by: shaping the surgical implant into its introduction configuration (Figures 9-10) but fails to explicitly disclose constraining the surgical implant progressively along its length by means of a jig to reduce the cross-section of said surgical implant while simultaneously covering the surgical implant in the sleeve in the closed configuration.

However, Campbell teaches that it is well known in the art to insert a surgical implant into a sleeve by shaping the surgical instrument into its introduction configuration by constraining the surgical implant progressively along its lengths by means of a jig to reduce the cross-section of the surgical implant while simultaneously covering the implant in the sleeve in the closed configuration (Figures 6D-F; column 6 line 66-Column 7, line 29).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method to include constraining the implant progressively by means of a jig as taught by Campbell, since such a modification reduces the cross-section of said surgical implant while simultaneously covering the surgical implant in the sleeve in the closed configuration

Response to Arguments

Applicant's arguments filed November 9, 2010 have been fully considered but they are not persuasive.

- Applicant argues that the device of Garren must have tension on the drawstring in order to keep the slit closed; wherein the tension needs to be maintained in order to maintain the slit in a locked position and therefore Garren does not disclose locking means capable on its own, without requiring any external action, of holding the cartridge in the closed configuration.

The Examiner respectfully disagrees. Garren discloses applying tension to the drawstring 38 to close the tube at the slit and nowhere discloses in the disclosure that the tension needs to be maintained in order to maintain the slit in a closed configuration. Additionally, at column 5, lines 16-19, Garren states that after the assembled tube is positioned inside the stomach, tension is applied to the drawstring to remove the drawstring and open the slit and therefore the tension is not applied during the introduction of the assembled device. Based on the broadest interpretation of the claim language, the claim does not preclude tensioning the string to close the slit but instead merely requires that the locking means is capable of holding the cartridge in a closed configuration. Therefore, since the tension is applied to close the tube and not to maintain the cartridge in a close configuration and the locking means (Ref 38) is capable of holding the cartridge in a closed configuration without requiring any external action, the arguments are not persuasive.

- Applicant argues that the device of Garren does not disclose a sleeve with a side opening formed along its length, since Garren only discloses a partial slit.

The Examiner respectfully disagrees and notes that the broadest interpretation of the claim language merely requires at least one side opening to be along the length and not that the opening extends the entire length. Since, the claim language does not exclude a partial opening that extends along the length, such as the slit in Garren, the arguments are not persuasive.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. C./
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3776